REMARKS

Claims 1-16 are pending in this application.

Claims 1-16 have been rejected.

In view of the following, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claims 1-16, have been rejected under 35 USC §103(a) as being unpatentable over Kluger et al. in view of Zhao et al.

The Examiner asserts that it would have been obvious to the skilled artisan to use a combination of the teachings of Kluger et al. along with the teachings of Zhao et al. to arrive at the claimed formulation because Kluger et al. describes a formulation for reducing the pH in a menstruating vagina by inserting a tampon made from solid organic acid polymer and solid organic acid and a wetting agent, and Zhao et al. teaches a flushable tampon applicator made from biodegradable components such as lactide copolymers and glycolide polymers.

In view of the remarks herein, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04–1350, 550 U. S. ____ (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an

apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, *supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Present claim 1 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, comprising: (a) 3-100% by weight of glycolide; (b) optionally, 97-15% by weight of a solid organic acid; and/or (c) optionally, 5-30% of a wetting agent. Glycolide is a ***cyclic dimer*** of glycolic acid, containing two ester groups which upon contact with an aqueous environment are hydrolyzed, resulting in two glycolic acid molecules (last paragraph on page 2 of the specification). Claims 2-10 and 12-15 are each directly or indirectly dependent on independent claim 1.

Present claim 11 is directed to a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5 comprising: (a) 3-100%

by weight of glycolide; (b) optionally, 3-97% by weight of lactide; (c) optionally, 97-15% by weight of a solid organic acid; and (d) optionally, 5-30% of a wetting agent. Claim 16 is dependent on claim 11.

It is submitted that a *prima facie* case of obviousness has not been established because neither Kluger et al. nor Zhao et al. teach or suggest all the limitations of the claims as required by *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970). Specifically, neither Kluger et al. nor Zhao et al. teach or suggest a formulation containing the cyclic dimer, glycolide. It is also submitted that a *prima facie* case of obviousness has not been established because the skilled artisan would have no motivation to combine the teachings of Kluger et al. and Zhao et al.

Kluger et al. discloses a formulation effective for reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, comprising (a) 3-80% by weight of a solid organic acid polymer; (b) 92-15% by weight of a solid organic acid, and (c) 5-30% of a wetting agent. Kluger et al. describes that suitable solid organic acid polymers can include polylactic acid, polyglycolic acid and polymalic acid.

Zhao et al. describes flushable tampon applicators that comprise a combination of thermoplastic materials that readily disintegrate in water for improved disposal and reduced environmental concerns.

It is submitted that the combination of Kluger et al. and Zhao et al. is improper because the skilled artisan concerned with the problem of reducing the pH in a menstruating vagina as described in Kluger et al., would have no motivation to look to Zhao

et al. which disclosure addresses the problem of providing environmentally safe, flushable, tampon applicators. Likewise, the skilled artisan concerned with the problem of providing environmentally safe, flushable, tampon applicators as described in Zhao et al., would have no motivation to look to Kluger et al. which disclosure addresses the problem of reducing the pH in a menstruating vagina.

Zhao et al. is concerned with a tampon applicator which does not remain in the vagina, has no relation to vaginal pH control and does not affect or alter the activity or properties of the tampon itself, whereas the presently claimed subject matter is concerned with a formulation for reducing the pH in a menstruating vagina or in a tampon inserted therein, as well as with a catamenial tampon comprising the formulation. Thus, Zhao et al. is not at all relevant to the field of the invention, and one of ordinary skill in the art reading Zhao et al. would not consider applying the teachings of Zhao et al. to the problem of reducing the pH in a menstruating vagina or in a tampon inserted therein. Nor would one of ordinary skill in the art consider combining Zhao et al. with Kluger et al., as they relate to two different arts, i.e. a tampon applicator (which is discarded) and a tampon, respectively.

In view of the above, it is submitted that a *prima facie* case of obviousness has not been established because the combination of Kluger et al. with Zhao et al. is improper. Accordingly, the Examiner is requested to withdraw this rejection.

Assuming *arguendo*, the combination of Kluger et al. with Zhao et al. proper, a *prima facie* case of obviousness has not been established because neither Kluger et al. nor Zhao et al. teach or suggest all the limitations of the claims as required by *In re Wilson.*

Kluger et al. discloses a formulation effective for reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, comprising in part, 3-80% by weight of a solid organic acid polymer. Kluger et al. ***does not*** teach or suggest the use of ***glycolide***. In fact, the term "glycolide" ***does not appear at all*** in Kluger et al. One of ordinary skill in the art would have no reason to use glycolide for the solid organic acid polymer based on the disclosure of Kluger et al.

As shown in the Examples set forth in the present specification, the use of glycolide imparts significant advantages to the presently claimed formulation which advantages are not found in the formulation of Kluger et al. For example, in the formulation of Kluger et al., the solid organic acid and the wetting agent are required components, whereas in claim 1 of the present application, they are optional components, and if present, may be used in the alternative. This is due to the unexpectedly superior pH reducing properties of glycolide (see Figs. 4 and 6 and the description in the paragraph bridging pages 7 and 8, and the 2nd full paragraph on page 8, of the present specification).

Zhao et al. does not remedy the deficiencies of Kluger et al. Zhao et al. describes flushable tampon applicators that comprise a combination of high molecular weight polyethylene oxides, low molecular weight polyethylene glycols, and biodegradable polymers that include glycolide polymers, including glycolide homopolymers and glycolide copolymers; and mixtures thereof. Zhao et al. ***does not*** teach or suggest the use of ***glycolide***, which, as stated above, is a ***cyclic dimmer.*** Zhao et al. does not relate at all to a pH reducing formulation, and the glycolide mentioned therein is a structural element rather than a functional element.

In view of the above, it is submitted that neither Kluger et al. nor Zhao et al., taken alone or together, teach or suggest a formulation including glycolide, as presently claimed.

In view of the foregoing, it is submitted nothing in Kluger et al. and Zhao et al., taken alone or in combination, renders the presently claimed subject matter obvious within the meaning of 35 U.S.C. § 103(a). Applicants respectfully submit a *prima facie* case for obviousness has not been established. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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